

Inventor : Shalaby et al.  
Serial No. : 09/762,431  
Filed : May 22, 2001  
Page : 9

**REMARKS**

This amendment is responsive to the Office Action mailed August 22, 2003 (hereinafter the "present Office Action"). Original claims 11, 12 and 19 are under examination in the present office action. Claims 2-10, 13-18 and 20-28 were previously withdrawn from consideration in compliance with the finding that the present application lacked unity as stated in the Office Action mailed November 20, 2002. Reconsideration of the present Office Action and allowance of the application, as amended, are respectfully requested.

1. In the present Office Action the Examiner states that she has not considered the Mao et al. reference cited on the Information Disclosure Statement filed May 20, 2003. Applicants respectfully direct the Examiner's attention to the PTO Form-1449 which accompanied said Statement wherein the Examiner placed her initials next to the Mao et al. citation confirming her review. In an effort, however, to the prosecution of this application, Applicants submit herewith a 3<sup>rd</sup> Supplemental Information Disclosure with accompanying PTO Form-1449 together with a copy of the Mao et al. reference, for the Examiner's review.

Inventor : Shalaby et al.  
Serial No. : 09/762,431  
Filed : May 22, 2001  
Page : 10

2. Claims 11, 12 and 19 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, said claims were found to be vague and indefinite for being dependent upon a canceled claim. Applicants have amended claim 11 as an independent claim having all the limitations of original claim 1 which it was previously dependent thereon. Applicants respectfully submit that this amendment overcomes the vagueness and indefiniteness and respectfully request the withdrawal of the 35 U.S.C. §112, second paragraph, rejection.

3. Claims 11 and 19 stand rejected under 35 U.S.C. 102 (a) or (e) as being anticipated by U.S. 5,686,540 issued to Kakizawa (hereinafter referred to as "Kakizawa").

The Court of Appeals for the Federal Circuit, in ruling on the standard for anticipation under 35 U.S.C. §102(b), has stated that

"[i]t is elementary that an anticipation rejection requires a showing that *each limitation* of a claim must be found in a single reference, practice, or device."

In re Donohue, 226 U.S.P.Q. 619 (1985) (*emphasis added*); and has further stated that

". . . exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference",

Inventor : Shalaby et al.  
Serial No. : 09/762,431  
Filed : May 22, 2001  
Page : 11

Atlas Power Co. v. E. I. duPont DeNemours & Co., 224

U.S.P.Q. 409, 411 (1984).

At page 3 of the present Office Action the Examiner states that Kakizawa exemplifies a lactic acid-based polyester comprising L-lactide/D-lactide (98/2), terephthalic acid, ethylene glycol, and tartaric acid. Pending claim 11, however, does not require that the polyester contain terephthalic acid and ethylene glycol, as does Kakizawa. The pending claims of the instant application contain a limitation, i.e. that terephthalic acid and ethylene glycol **are not present** in the claimed polyester chain, which is absent from Kakizawa. Accordingly, the rejection based on 35 U.S.C. §102(a) or (e) is obviated, and therefore should be withdrawn.

Applicants acknowledge the Examiner's comments found in the 1<sup>st</sup> paragraph of page 4 of the present Office Action with respect to claimed intended use. As stated previously, the intended use of the claimed polyester, i.e. that they be absorbable, is not the distinguishing factor between the present polyesters and those of Kakizawa.

4. Claim 12 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Kakizawa (see above). Applicants assert that this is a new ground of rejection since claim 12 was deemed allowable in the 1<sup>st</sup> Office Action (Paper 11).

Inventor : Shalaby et al.  
Serial No. : 09/762,431  
Filed : May 22, 2001  
Page : 12

As such, the finality of the present application is premature. According to the provisions of MPEP §706.07 (a), [a] second or any subsequent actions on the merits shall be final, **except where the examiner introduces a new ground of rejection** that is neither necessitated by applicants' amendment of the claims nor based on information submitted in an information disclosure statement. It should be noted that claim 12 has never been amended and that U.S. 5,686,540 has never been reported on any information disclosure statement. The provisions allowing for a final rejection based on Kakizawa are not, therefore, present in this instance. Applicants request the reconsideration of the finality of the rejection of the present Office Action and ask the withdrawal thereof.

Notwithstanding, the polyesters of the present application would not be obvious based on the teachings of Kakizawa. The Examiner, in support of her finding, states that only the difference between the polyesters of the present application and those of Kakizawa is the presence of polyethylene glycol. The examiner reasons that since

Inventor : Shalaby et al.  
Serial No. : 09/762,431  
Filed : May 22, 2001  
Page : 13

Kakizawa teaches the use of ethylene glycol, the substitution of polyethylene glycol, would be obvious to one skilled in the art.

Applicants respectfully assert that the Examiner does not appreciate the inventiveness of the present application. As stated on page 7 of the Specification, the present application is directed to absorbable polyesters having at least one monophosphate functionality per polyester chain. The purpose for incorporating the monophosphate functionality is to provide two acid -OH groups capable of ionically and/or covalently conjugating with the basic amine groups of bioactive agents such as peptides and proteins. See present application at page 7, lines 10-12. Compare that to Kakizawa wherein "an acidic phosphoric acid ester may be used ... to [complex] metal ions in the catalyst contained in the lactic acid-based polyester composition to **deactivate** the catalyst and hence exert a great effect of inhibiting the break of polymer chains." See Kakizawa at column 8, lines 59 - 64. There is no teaching, inference or suggestion in Kakizawa to covalently bond a monophosphate functionality to a polyester so as to provide two free -OH groups capable of bonding to a bioactive agent.

Inventor : Shalaby et al.  
Serial No. : 09/762,431  
Filed : May 22, 2001  
Page : 14

The CAFC has required that an obviousness rejection be supported by some suggestion in prior art to create the claimed invention, stating -

"[A] proper analysis under §103 requires, *inter alia*, consideration of . . . whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed invention",

*In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) (emphasis added).

The Examiner has cited no prior art which would support such a suggestion in this case, i.e., that one of ordinary skill in the art should bond a monophosphate functionality to an absorbable polyester chain so as to provide two free -OH groups capable of binding to a bioactive agent as claimed in the instant application. Applicants, therefore, submit that the rejection of claim 12 under 35 U.S.C. §103 based on Kakizawa is improper and should be withdrawn. Without conceding the correctness of this rejection and solely in an effort to put this application in a condition of allowance, however, Applicants have amended pending claim 11 to better distinguish it from Kakizawa.

5. Applicants respectfully request the rejoinder of withdrawn claims 2-10, 13-18 and 20-28. Claims 2-10, 13-18 and 20-28 were withdrawn in response to a prior finding

Inventor : Shalaby et al.  
Serial No. : 09/762,431  
Filed : May 22, 2001  
Page : 15

that the present application lacked the requirements for "unity of invention" under PCT Rule 13.

The present application is a national stage application under 35 U.S.C. 371 of PCT International Application PCT/US99/18146. As such, unity of invention, rather than restriction, practice is applicable. See MPEP §1893.03(d). Rule 13 (Unity of Invention) of the Regulations under the PCT states that the requirement of unity is fulfilled when "there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." See Rule 13.2, Regulations under the PCT.

Applicants respectfully submit that the Examiner has not carried her burden to support the restriction requirement. MPEP §803 states that "under the statute an application may properly be required to be restricted...only if [the separate inventions] are able to support separate patents and they are either independent... or distinct." The claims of the present application are all directed compositions having absorbable polyesters having at least one monophosphate functionality which provide free -OH groups capable of bonding to bioactive agents. The most relevant prior art identified by the Examiner, i.e. Kakizawa, does not destroy the novelty or inventiveness of

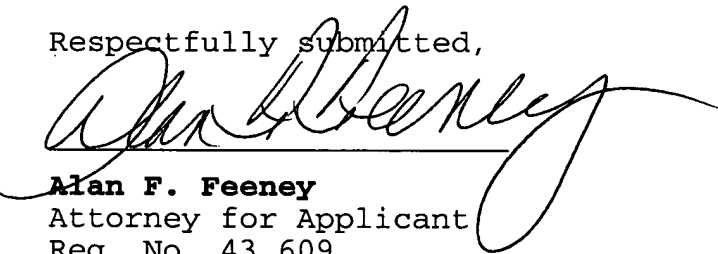
Inventor : Shalaby et al.  
Serial No. : 09/762,431  
Filed : May 22, 2001  
Page : 16

the polyesters of the present application. As such, the separate inventions of the present application are so linked so as to form a single inventive concept. For the foregoing reasons, the Applicants submit that the restriction made in the prior Office Action was improper and respectfully requests the rejoinder of the withdrawn claims.

### Conclusion

Based on the above remarks, Applicants submit that all of the rejections and objections have been overcome and that all pending claims are now in a condition for allowance, which action is respectfully requested. Should Examiner Wells deem that any further action by the Applicants would put this application in order for acceptance, she is requested to contact the Applicants' undersigned representative.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0590.

Date: 2-20-2004 Respectfully submitted,  
  
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